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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,254	11/15/2001	John C. Reed	P-LJ 5037	8329
23601	7590	10/14/2004	EXAMINER	
CAMPBELL & FLORES LLP 4370 LA JOLLA VILLAGE DRIVE 7TH FLOOR SAN DIEGO, CA 92122			NICKOL, GARY B	
		ART UNIT	PAPER NUMBER	
		1642		

DATE MAILED: 10/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,254	REED ET AL.	
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 July 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 14-16, 18, 23 and 53-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-16, 18, 23 and 53-62 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input checked="" type="checkbox"/> Other: <u>Sequence alignments</u> . |

Re: Reed *et al.*

Date of Priority: November 17, 2000

Response to Amendment

The Amendment filed 07-28-04 in response to the Office Action of 01-28-04 is acknowledged and has been entered.

Claims 1-13, 17, 19-22, and 24-52 were cancelled.

Claims 53-62 were added.

Claims 14-16, 18, 23, and 53-62 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Rejections Maintained:

Claims 14-18, and 23 remain rejected and new claims 53-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record in the Action mailed 01/28/04, pages 6-8.

Applicants argue (Response filed 07-28-04, page 8), that the claims, as amended, are now limited to those nucleic acids “consisting of” DNA encoding the amino acid sequence of SEQ ID NO:6. Applicants submit that the specification would have been more than adequate to convey to the person skilled in the art that the inventors had possession of the claimed invention. This argument has been considered but is not found persuasive. Amending the claims to consisting of does not address the written description guidelines as set forth in the previous rejection. As set forth previously, only an isolated nucleic acid molecule encoding a polypeptide selected from the group consisting of SEQ ID NOs:6 and or the complete complements thereof, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Currently, the claims encompass any and all complementary nucleic acid sequences that share the ability to encode SEQ ID NO:6 wherein such nucleic acids would hybridize under moderately stringent conditions. However, as set forth previously, the specification fails to sufficiently describe the genus of nucleic acids that hybridize under moderately stringent conditions to nucleic acids encoding SEQ ID NO:6. Further, the hybridization conditions as disclosed by the specification are not limiting and thus the claims read on the full range of conditions from low to highly stringent wherein the claimed hybridized polynucleotides read on polynucleotides that range from those that lack significant complementarity to those that are completely complementarity to the claimed complementary polynucleotide. Thus, the claims remain inclusive to a **genus** of polynucleotides. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

Claims 14-16, and 23 remain rejected under 35 U.S.C. 102(a) as being anticipated by Watanabe *et al.* (GenEmbl/PRI Database, Accession No. AK000528, February 22, 2000). As set forth previously, Watanabe *et al.* teach an isolated nucleic acid molecule encoding a polypeptide that is 100% identical to SEQ ID NO:6 (see attached sequence listing).

Applicants argue (Response, 07-28-04, page 9) that nothing in the Watanabe reference teaches or suggests the existence of a DD domain polypeptide. Nor does the Watanabe reference teach or suggest nucleic acids consisting of a DNA encoding a DD domain polypeptide. Thus, Applicants submit that the claims as amended are not anticipated by Watanabe. This argument has been considered but is not found persuasive as the reference clearly anticipates an isolated nucleic acid sequence that consists of a sequence selected from DNA encoding the amino acid sequence set forth in SEQ ID NO:6 and or DNA that hybridizes to the DNA of the latter under moderately stringent conditions. The amended language “consisting of a sequence” fails to adequately distinguish the prior art sequence from the claimed nucleic acid(s) because the prior art sequence still encodes SEQ ID NO:6, and the *claimed* nucleic acid encompasses **any** sequence (consisting or comprising or having) nucleic acids that encode SEQ ID NO:6. In other words, there is no attempt to define the nucleic acid by SEQ ID NO, such as in newly amended Claim 18. Thus, applicant’s arguments have not been found persuasive and the rejection is maintained.

Claims 14-16, 23 remain rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,440,663 (Scanlan *et al.*, October 1998). Applicant’s arguments are substantially similar to those set forth above and are not found persuasive for the reasons of record.

NEW REJECTIONS:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 53, 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe *et al.* (GenEmbl/PRI Database, Accession No. AK000528, February 22, 2000) or US Patent No. 6,440,663 (Scanlan *et al.*, October 1998) in view of the teachings of Matthews *et al.* (Anal.Biochem., Vol. 169, Feb. 1988, pp.1-25).

Both Watanabe *et al.* and Scanlan *et al.* teach an isolated nucleic acid molecule consisting of a sequence selected from the group consisting of DNA encoding the amino acid sequence set forth in SEQ ID NO:6; and DNA that hybridizes to the latter under moderately stringent conditions.

Neither reference specifically teaches the inclusion of labels linked to the DNA such as fluorescent labeling, radioactive elements, or enzymatic labels.

Matthews *et al.* teach a review of analytical strategies for the use of DNA probes that includes labeling with radioactive, enzymatic, and or fluorescent agents.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to link the nucleic acids of the prior art with radioactive, fluorescent, and or

enzymatic agents. One would have been motivated to do so because Matthews *et al.* teach that labeling nucleic acids are conventional in the art for the purposes of quantitation, hybridization, and localization (pages 1, and 5-10). Such labeling includes fluorescent labeling, radioactive elements, and enzymes such as horseradish peroxidase and glucose oxidase.

Claims 59-62 are rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of a nucleic acid that consists of a “chimeric non-naturally occurring DNA consisting of first and second DNA fragments” has no clear support in the specification and the claims as originally filed, including pages 28-32 as suggested by Applicants in their response filed 07-28-04, page 6. Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the “limitation” indicated above. See MPEP 714.02 and 2163.06.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection/objection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

Art Unit: 1642

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

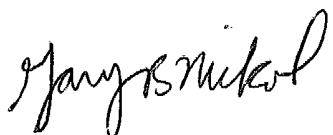
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN


GARY NICKOL
PRIMARY EXAMINER

Command line parameters:
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Pred. No. is the number of results predicted by chance to have a score greater than or equal to the score of the result being printed, and is derived by analysis of the total score distribution.

SUMMARIES

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1	517	100.0	833	4	US-09-166-350-10	Sequence 10, Appli	
2	96.5	18.7	2288	3	US-09-135-232-1	Sequence 1, Appli	
3	96.5	18.7	2288	4	US-09-163-349-1	Sequence 1, Appli	
4	79	15.3	1806	2	US-08-980-060-1	Sequence 1, Appli	
5	79	15.3	1806	3	US-08-980-060-1	Sequence 1, Appli	
6	79	15.3	3459	2	US-08-980-060-3	Sequence 3, Appli	
7	79	15.3	3459	3	US-09-107-185-3	Sequence 14, Appli	
C	8	78.5	15.2	479	2	US-08-980-060-14	Sequence 14, Appli
C	9	78.5	15.2	479	3	US-09-207-185-14	Sequence 14, Appli
C	10	72	13.4	536165	4	US-09-14-808-1	Sequence 1, Appli
C	11	69.5	13.4	1416	3	US-09-334-393-26	Sequence 26, Appli
C	12	69.5	13.4	1416	4	US-09-360-545-19	Sequence 19, Appli

ALIGNMENTS

RESULT 1
 US-09-166-350-10
 Sequence 10, Application US/09166350A
 ; Patent No. 6140632
 ; GENERAL INFORMATION:
 ; TITLE OF INVENTION: Renal Cancer Associated Antigens and
 ; FILE REFERENCE: L0161/T051
 ; CURRENT APPLICATION NUMBER: US/09/166-350A
 ; EARLIER APPLICATION NUMBER: US 09/166,350
 ; EARLIER FILING DATE: 1998-10-05
 ; NUMBER OF SEQ ID NOS: 35
 ; SEQ ID NO: 10
 ; LENGTH: 833
 ; TIPS: DNA
 ; ORGANISM: Homo sapiens
 US-09-166-350-10

Data encoding seq ID #6

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 Best Local Similarity: 100.00%
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US-10-001-254-6 (1-98) x US-09-166-350-10 (1-833)

